

DETAILED ACTION

This application filed 01/25/2006 is a 371 of PCT/US04/24387 08/18/2004 which claims benefit of 60/496,537 08/20/2003.

However, no disclosure relevant to the elected group in this prosecution is found in the above-indicated provisional application. PCT/US04/24387 08/18/2004 does have disclosure relevant to the instant elected group.

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 02/28/2008 is acknowledged.

In a telephone conversation on 04/11/2008 with Tini Thomas 973 532-8021, agreement was reached by the Examiner to prosecute claims 1-11 drawn to compounds of the formula I wherein Y = S.

The Examiner notes that of the 11 claims 1-4, 7,8 pertain to formula I wherein Y = S.

The above-mentioned traversal is on several grounds.

Initially, the applicant points out that the restriction is incorrect because if Y = S, R5 can not exist.

In the above-mentioned conversation with Tini Thomas, the Examiner clarified that the Groups I and II of the Restriction correspond to thiophene compounds, i.e., Y = S. As such the current prosecution relates to compounds wherein Y = S of formula I.

Applicant states that the restriction should be withdrawn in light of the particulars of EP 1 658 273 B1 which claims priority to the provisional application and PCT application of the instant case. The instant claims are prosecuted as per US rules and regulations which are not identical to the rules and regulations of the international authority.

Applicant's arguments on the basis of classification is confusing at best. For example applicant's classification of Examiner's groupings do not agree with the US Classification. None of the numbers on page of 3 of applicants remarks are anywhere close to the numbers (of class 549, 546 or 544 depending on Y and X of the formula and the corresponding pharmaceutical compositions in class 514) attributable to the Examiners Groupings based on US classification system. Thus applicant's arguments are unclear.

The applicant further states that

Examiner Does Not Allege That Examination Of Claims Sharing The Same Classification Would Impose A Serious Burden.

In response to the above, the Examiner draws the applicant's attention to page 3, lines 14-16 of the restriction requirement which states that

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction were not required; because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

For these reasons the applicant's arguments are not persuasive and the requirement is deemed proper and is therefore made FINAL.

Claims 1-4, 7 and 8 are drawn to compounds of formula I wherein Y = S.

Claims 1-4, 7 and 8 drawn to compounds of formula I wherein Y = S correspond to Elected Group.

As noted earlier, this group of compounds (thiophene compounds) are not found in the provisional application 60/496,537. As such the priority date for prosecution purpose is the international filing date of PCT/US2004/024387 08/18/2004 which contains compounds of the Elected Group.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 and dependent claims rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Formula I of claim 1 is drawn to X, defined as a five membered aromatic heterocycle that "contains at least two or three heteroatoms selected from N,S,O wherein at least one heteroatom must be N". It is unclear, for example, what are the five membered heteroaromatics the applicant is seeking protection for that could have more than one O or S atoms. The definition of X encompasses impossible substituents.

If a substituent is impossible, the claim can properly be rejected under 35 USC paragraph 1 or 2.

A compound with an impossible substituent clearly cannot be made, and hence a paragraph 1 rejection is proper. Alternatively, if it is impossible, then it is not correct. As stated in *In re Zletz*, 13 USPQ2d 1320, 1322, "An essential purpose of patent examination is to fashion claims that are precise, clear, correct and unambiguous."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

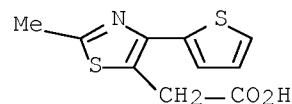
A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

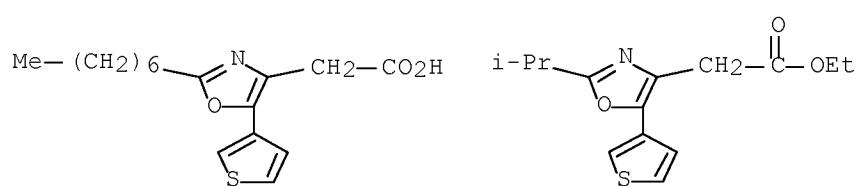
Claim 1-4, and 7 rejected under 35 U.S.C. 102(b) as being anticipated by prior art.

Some of the prior art references for instantly claimed compounds are shown below:

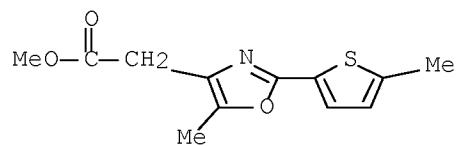
Knott, Edward B. US 2423709



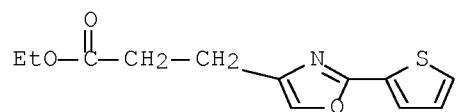
Moriya et al. Journal of Medicinal Chemistry (1988), 31(6), 1197-1204



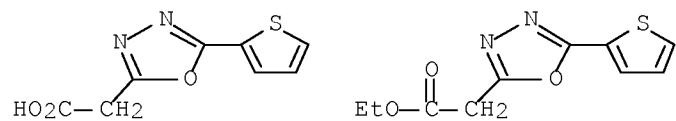
Willson et al. US 6294580



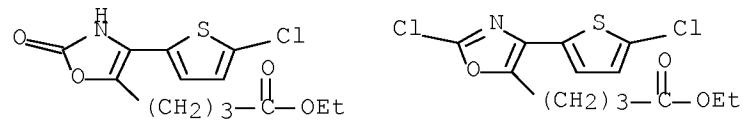
Momose et al. US 6211215



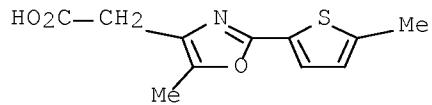
Janda et al. Heterocyclic Communications (2001), 7(5), 411-416



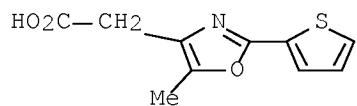
Momose et al. US 6605629



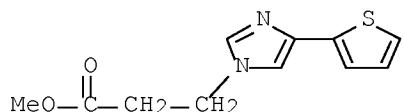
Brooks et al., US 6930120



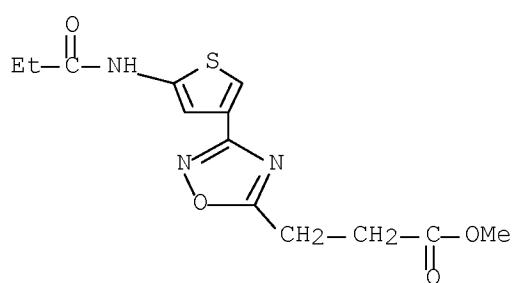
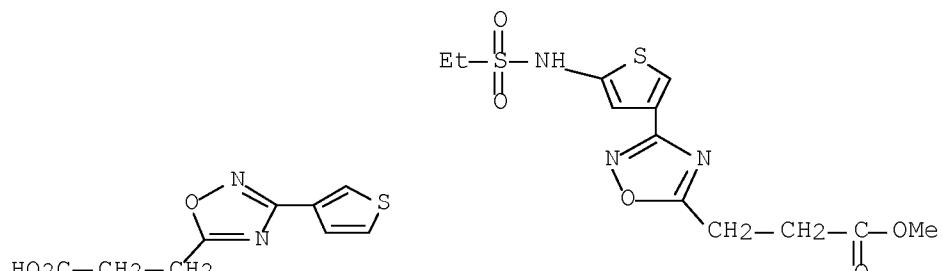
Brooks et al., US 6982278



Andreotti et al. WO 2002050091



Beaton et al. US 6924284



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

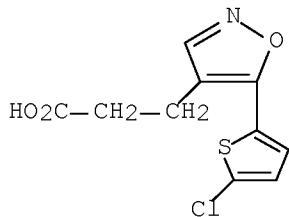
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

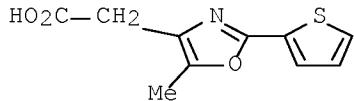
Claims 1-4, 7 and 8 rejected under 35 U.S.C. 103(a) as being obvious over Momose et al. (US 6605629 & US 7022725) further in view of Brooks et al. (US 7351728)

The instant compounds are drawn to compounds in which a thiophene ring is bonded to a variety of aromatic 5-membered heterocycles that could have utility in treating a variety of diseases including diabetes related complications (see page 4 of the specification).

Momose et al. teach compounds in which a thiophene ring is bonded to a aromatic 5-membered heterocycle, for example,



Brooks et al. teach compounds in which a thiophene ring is bonded to a aromatic 5-membered heterocycle, for example,



Momose et al. teach that these compounds have excellent insulin secretion-promoting and blood sugar-decreasing effects and low toxicity and are useful as drugs, particularly preventive and therapeutic agents for diabetes and diabetic complication.

Likewise, Brooks et al. teach the antidiabetic use of his compounds.

Momose et al. and Brooks et al. do not teach all the instantly claimed 5-membered heterocyclic variations or assert that the biochemical mechanism underlying the observed biological activity of their compounds are the same as instantly claimed.

However, one skilled in the art of medicinal chemistry would be motivated to make additional analogs of Momose et al. by modifying the 5-memebered heterocyclic X part to arrive at applicants compounds because Brooks et al. teach that the nature of the 5-membered heterocycle does not alter the antidiabetic activity. Many of the rejections under 35 U.S.C. 102(b) are also applicable as prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 7 and 8 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making one compound pertaining to the elected group, does not reasonably provide enablement for the plethora of possibilities claimed. For example there is found in the speciation enabling disclosure on how to make only one single compound (see page 9 of the specification), which corresponds to the formula I R1 = R2 = H, X = 2,4-disubstituted oxazole, n = 4. Another working

example, on page 10 relates to a patentably same compound (acid corresponding to the ester on page 9)

Esters were held unpatentable over the prior art free acid because the idea of modifying carboxyl groups of compounds isomeric to the claimed compound was taught in another reference and no unusual utility inherent in the claimed esters was shown. *Ex parte Bergel et al.* (POBA 1949) 121 USPQ 522; *In re Ward* (CCPA 1964) 329 F2d 1021, 141 USPQ 227.

Further, no enabling disclosure with respect to making the specifically claimed compound of claim 8 is found in the specification; m/z found for this compound on page 10 could have been ascertained by means other than Mass Spectroscopy that requires sample of the compound.

It is also not seen where in the specification, enablement is present with respect to biological activity of the claimed compounds. What could be found in the specification is academic teachings of biological assay procedures that could be used to assay the compound. The last lines in the specification appears to relate to real world utility of the compounds of formula (IIa on page 10); however, it is unclear whether the 'representative compounds' of formula II(a) alleged to have improved area AUC relate to the Elected group of thiophene compounds or the non-elected pyridine derivatives.

The specification thus does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIZAL S. CHANDRAKUMAR whose telephone number is (571)272-6202. The examiner can normally be reached on 8.30 AM - 4.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571 0272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nizal S. Chandrakumar

/D. Margaret Seaman/

Primary Examiner, Art Unit 1625